





UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
00/253 153	02/19/1900	ALAN W SCHWARACHER		5283

7590

05/08/2002

KAROLINE K M SHAIR CHOATE HALL & STEWART EXCHANGE PLACE 53 STATE STREET BOSTON, MA 02109 EXAMINER
BAKER, MAURIE GARCIA

3/-

ART UNIT PAPER NUMBER

1627

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. **09/253,153**

Applica:...

Schwabacher

Examiner

Maurie E. Garcia, Ph. D.

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The MAILING DATE of this communication appears on the cover sheet with the correspo	ongence aggress
Period for Reply	(A) EDOM
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>THREE</u> MONTH THE MAILING DATE OF THIS COMMUNICATION.	I(S) FROM
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SI3	(6) MONTHS from the
mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be consider	
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 13	f this communication.
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any	, , , , , , , , , , , , , , , , , , ,
earned patent term adjustment. See 37 CFR 1.704(b). Status	
1) X Responsive to communication(s) filed on Oct 1, 2001	
2a) ☐ This action is FINAL . 2b) ☒ This action is non-final.	•
3) Since this application is in condition for allowance except for formal matters, prosecution closed in accordance with the practice under Ex parte Quay/1935 C.D. 11; 453 O.G. 213	as to the merits is
Disposition of Claims	
4) X Claim(s) <u>1-7 and 37-46</u>	_ is/are pending in the applica
4a) Of the above, claim(s)	is/are withdrawn from considera
5)	
6) ☑ Claim(s) <u>1-7 and 37-46</u>	
7)	is/are objected to.
8) Claims are subject to re	estriction and/or election requirem
Application Papers	
9) The specification is objected to by the Examiner.	•
10) The drawing(s) filed on is/are a accepted or b objected t	o by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR	
11) The proposed drawing correction filed on is: a 'approved b)	
If approved, corrected drawings are required in reply to this Office action.	
12) The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. §§ 119 and 120	
13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:	
 Certified copies of the priority documents have been received. 	
2. ☐ Certified copies of the priority documents have been received in Application No	•
 Copies of the certified copies of the priority documents have been received in this N application from the International Bureau (PCT Rule 17.2(a)). 	ational Stage
*See the attached detailed Office action for a list of the certified copies not received.	
14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	•
a) The translation of the foreign language provisional application has been received.	
15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or	[*] 121.
Attachment(s)	
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s) (PTO-413) Paper No(s) (PTO-413) Paper No(s)	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	132)
3) Aminomation Disclosure Statement(s) (F10-1443) Fabri No(s). 1 0) Domei.	

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DETAILED ACTION

Continued Prosecution Application

- 1. The request filed on June 8, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/253,153 is acceptable and a CPA has been established. An action on the CPA follows.
- 2. The previously unentered amendment filed April 9, 2001 has now been entered. Claims 1-3 were amended in this Response and claims 8-36 were cancelled. Therefore, claims 1-7 and 37-46 are currently pending and under examination.

Specification-Sequence Listing

3. The examiner acknowledges the corrections made in the amendment filed 10/1/01. The application now complies with the requirements of 37 CFR 1.821 through 1.825.

Objections

4. The disclosure is objected to (page 21, line 28) because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

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- 5. The use of the trademark "Kevlar" has been noted in this application (page 6, line 8 and elsewhere). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.
- 6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

- 7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 8. Claim 1-7 and 37-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the invention as now claimed. The claims now recite that "the chemical compounds

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are not intermediates leading to a single final product" (claim 1) and/or various limitations based on "first [and additional] set of reagents or reaction conditions" "first [and second] specific spatial period" and "first [and additional] set of compounds" where each compound within the set "being related to all other compounds in the first [or additional] set as a product of the first set of reagents or reaction conditions". There simply does not appear to be support for the specific limitations now claimed and Applicant has not pointed to support. In accordance with MPEP § 714.02, applicants should **specifically point out support** for any amendments made to the disclosure. Also, in order for a negative limitation to be added to a claim, that particular limitation must be specifically recited in the specification.

- 9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 10. Claims 1, 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - A. Claim 1 recites "the chemical compounds are not intermediates leading to a single final product". This is deemed to be confusing as it is unclear as to applicant's intent. Since the "intermediate", "final product" and also the reaction in question are not defined by the claim, one of ordinary skill could not determine

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whether or not the chemical compounds would lead to the same or different final products.

B. Claims 3 and 4 are deemed to be indefinite because there is unclear antecedent basis in the claims. Claim 3 recites "reactive functional groups" and claim 4 (which depends from claim 3) recites "reactive moieties" and "additional functional groups". It is unclear how these moieties relate to one another (are they the same?). Clarification is requested.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 12. Claims 1-7, 37, 38 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Lebl et al (EP 0 385 443 A2: listed on PTO-1449, Paper No. 2).

Please note the following. As the meaning of the newly added limitation that "the chemical compounds are not intermediates leading to a single final product" is unclear (see rejection under 35 U.S.C. 112, second paragraph above), the below rejection is maintained. The instant claims can be interpreted as follows: any chemical compound could be an intermediate for a variety of different reactions, leading to a variety of different final products.

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Lebl et al discloses a method for synthesizing oligomers on a solid support that is in the form of a band, thus forming "an array of chemical compounds" (see Abstract and Fig. 1, reference numeral 1 of the patent). The band carrier of Lebl et al is "led, e.g. by means of a series of rollers, through the appropriate reagents and washing solvents so that individual reactants are step-wise bonded" (see page 4, lines 30-34). Furthermore, in the process of Lebl the steps proceed at locally different sites (see page 4 lines 35-38). The arrays of Lebl et al are subjected to reaction conditions such as coupling of amino acids (for example) by deprotection and activation. These steps "cycle" along the support as a function of a unique distance and time (defined by the cycle through the system - see Figure 1 and page 5, lines 12-29) and clearly involve more than one reagent. See, for example, Example 10 of Lebl et al on page 9. Also, conventional protecting groups for peptide chemistry are used in the syntheses (see, for example, page 4, lines 39-46). The carriers can be those such as thread (see claims 1 and 5 of Lebl et al) which are "one-dimensional".

Additionally, the examiner respectfully points out that claims 2-4 and 6 are product-by-process claims and that any "array of chemical compounds" reads on such claims. The <u>process</u> by which the claimed array is synthesized does not appear to lend patentable weight to the claimed invention. One of ordinary skill would expect the array to be the same regardless of the manner of synthesis.

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13. Claims 1-3, 5-7, 37 and 42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Browne et al (Anal. Chem. 1996).

Browne et al disclose an "intrinsic sol-gel clad fiber optic sensor" (see Title and Abstract) which reads on the claimed "array of at least two chemical compounds attached to a support" as set forth below. The reference discloses that the "active sensor region of a fiber can be either immobilized at the distal end of an optical fiber (extrinsic) or distributed along the length of the fiber-optic waveguide (intrinsic)" (page 2289, 1st column, bottom). Specifically, Browne et al disclose a sol-gel clad optical fiber (see page 2291; Figure 1 and 1st column under 'Experimental Section; Sol-Gel Matrix'). The fiber of the reference reads on the claimed support and an array on such a fiber would inherently have "linear organization" due to the nature of the fiber.

The above-described fibers of Browne et al have sol-gel clad regions of the fiber that are created by removing the cladding from a silicone clad fiber and then replacing it with sol-gel cladding in the regions where the silicone was removed (see page 2291 1st column under 'Experimental Section; Sol-Gel Clad Fiber'). Several different dyes were used as dopants in the sol-gel regions; these dyes read on the claimed "array of at least two chemical compounds". Browne's purposely created regions of sol-gel clad fiber correspond to the claimed "regions" using different "reagents" of instant claims 2, 3 and 6. The fiber shown on page 2292 of the reference (in Figure 3 and discussed under section denoted (b)) reads specifically on the claimed array of agents as it shows a fiber that has

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four regions with attached AA and CV dyes that are spatially (linearly or onedimensionally; i.e. claims 7 & 37) resolved.

Additionally, the examiner respectfully points out that claims 2-4 and 6 are product-by-process claims and that any "array of chemical compounds" reads on such claims. The <u>process</u> by which the claimed array is synthesized does not appear to lend patentable weight to the claimed invention. One of ordinary skill would expect the array to be the same regardless of the manner of synthesis.

Claim Rejections - 35 USC § 103

- 14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 15. Claims 1-7 and 37-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebl et al (EP 0 385 443 A2: listed on PTO-1449, Paper No. 2) or Browne et al (Anal. Chem. 1996) in view of Lebl et al (US 5,688,696: listed on PTO-1449, Paper No. 2).

The teachings of Lebl et al (EP 0 385 443 A2) and Browne et al (Anal. Chem. 1996) are set forth supra. The Lebl reference teaches a method for synthesizing oligomers on a solid support that is in the form of a band, thus

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forming "an array of chemical compounds". The Browne reference teaches an optical fiber that has four regions with attached AA and CV dyes that are spatially (linearly or one-dimensionally; i.e. claims 7 & 37) resolved.

The references lack the teaching of duplicate compounds in different positions as set forth in the instant claims 38-42.

However, it was well known in the art at the time of the invention to make duplicate arrays of compounds. For example, Lebl (US 5,688,696) teach making arrays of compounds on a similar, one-dimensional carrier (thread; see column 7, lines 30-67). Lebl (US 5,688,696) makes these arrays in duplicate (see column 8, lines 9-42) so that a control can be used in the screening of the library.

Therefore, it would have been prima facie obvious to make the one dimensional array of chemical compounds as taught by Lebl et al (EP 0 385 443 A2) or Browne et al using any number of duplicate compounds. Lebl (US 5,688,696) teach that duplicate compounds in combinatorial chemistry arrays are advantageous in the screening process. Thus, one would have been motivated to use duplicates in the array of by Lebl et al (EP 0 385 443 A2) as taught by Lebl (US 5,688,696) to assist in screening of the compounds of the array.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

- 17. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).
- 18. Claims 1-7 and 37-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6-13 and 30--50 of copending Application No. 09/535,300. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. The instant claims would be obvious to one of ordinary skill in view of the claims of the co-pending application based on the fact that the instant case claims an array of compounds on a support and the co-pending case claims a similar array with the only difference being the more specifically defined support (fiber).

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

- 19. Applicant's arguments filed April 9, 2001 have been fully considered but are not found persuasive. The arguments are mainly moot in view of the new grounds of rejection stated in this action. However, the following is noted.
- 20. Applicant argues that the instant claims are distinguished from Lebl based on the newly added limitation of "the chemical compounds are not intermediates leading to a single final product". This is deemed to be both unclear (see rejection under 35 U.S.C. 112, second paragraph above) and to be new matter (also see rejection above). Also, since any chemical compound could be an intermediate for a variety of different reactions, leading to a variety of different final products, the rejection over Lebl under 35 USC 102 is maintained.

Status of Claims/Conclusion

- 21. No claims are allowed.
- 22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.

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23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D. May 6, 2002

MAURIE E. GARCIA, PH.D